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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,486	11/20/2000	Chet M. Crump	BAL-66-CON	8937

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EXAMINER	
WEISS JR, JOSEPH FRANCIS	
ART UNIT	PAPER NUMBER

3761

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,486	Application(s) Crump et al.	
	Examiner Joseph Weiss	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Nov 20, 2000

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Nov 20, 2000 is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u>	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Priority

1. This application repeats a substantial portion of prior Application No. 09/157605, filed 21 Sep 98, and adds and claims additional disclosure not presented in the prior application; the valve comprising an occluder and tether of claims 10-12. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the occluder & tether of claims 10-12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The terms/structures of a tether & occluder are not set forth in the written description but are used in claims 10-12.

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Claim Rejections - 35 USC § 112

4. Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims set forth a valve comprising a tether and occluder, which were not described in the parent application's written description in such a manner as to reasonably convey to one of skill in the art that these features were aspects of the invention applicant had in his possession at the time the parent application was filed. Such subject matter should be entered in a Continuation in Part application and not an "straight" continuation from the parent.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1, the last paragraph applicant sets forth that the valve is configured in the adapter to isolate the catheter from the manifold by withdrawing the end of the catheter "into" said manifold. This statement is self contradictory and does not make sense. How can one isolate an element from another element bu withdrawing it into the element that one is attempting to isolate it from? Does applicant mean into said adapter??

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In regards to claims 10-12, the claims are indefinite in light of the issue of the objection to the specification, because claims are read in light of the specification, the absence of a teaching of what applicant intends to be the valve comprising a tether & occluder can only be speculated about at best and hence indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Russo (US 5775325).

In regards to claim 1, Russo discloses a respiratory suction apparatus comprising a suction catheter (31) for removing fluids from a respiratory tract of a patient by insertion of the distal end (44) of the catheter into a patient's respiratory tract and withdrawal of the distal end of the catheter through a portion of the tract while applying negative pressure to the lumen of the catheter (see the background & summary of the invention); a protective sleeve (47) surrounding a proximal longitudinal portion of the catheter (See figs 4-7); a distal adapter (26, 32, 42 & 48, see figs 4-7) configured for fluid communication with a manifold (2-4) of a patient's artificial airway; a collar (32) disposed within the adapter and partially surrounding the distal end of the catheter

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when the catheter is withdrawn from the manifold, the catheter and the collar defining a substantially uniform cylindrical space around the distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter (see fig 6); and a valve device (26/28) configured in the adapter to substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter into the adapter and applying suction through the catheter lumen (See fig 6 & supporting text).

In regards to claim 2, Russo discloses the valve device as comprising a flap valve (note the flaps of element 28) disposed distal to a distal end of the collar.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3-7 & 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo.

In regards to claim 3, the flaps of Russo are seated against the collar by dint of being attached to element 26, which is seated against the collar (32) throughout the operation, thus to include when the negative pressure is applied.

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In regards to claim 4, the flaps of Russo are fully capable of seating against the distal end of the suction catheter upon application of suction through the catheter lumen.

In regards to claim 5, Russo discloses a cleaning enclosure (fig 6, interior of the adapter less the volume beyond the location of valve relative to the distal tip of the catheter) wherein the structure is fully capable of exposing the distal end to both cleaning liquids and turbulent air flow during a cleaning procedure. (See valve 38)

In regards to claim 6, the valve device of Russo (26/28) is disposed distal to the collar and comprises an aperture (the slit of 28) which is fully capable of establishing turbulent airflow.

In regards to claim 7, Russo discloses the valve device (26) seated against the distal end of the collar. (See the interface between 26 & 32).

In regards to claim 10, Russo discloses a respiratory suction apparatus comprising an elongated suction catheter (31) with a distal end (44); a protective sleeve (47) surrounding a proximal longitudinal portion of the catheter (See figs 4-7); a distal adapter (26, 32, 42 & 48, see figs 4-7) configured for fluid communication with a manifold (2-4) of a patient's artificial airway; a collar (32) disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the catheter and the collar defining a substantially uniform cylindrical space around the distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter (see fig 6, note interface w/ 37); a cleaning enclosure (fig 6, interior of the adapter less the volume beyond the location of valve relative to the distal tip of the catheter) wherein the structure is fully capable of exposing the distal

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end to both cleaning liquids and turbulent air flow during a cleaning procedure; a means for providing a predetermined rate of airflow to the enclosure responsive to negative pressure within the catheter (valve 38), the catheter being protected at all times against the environment from contamination by a combination of the sleeve, adapter and enclosure; and a valve device (26/28) comprised of an occluder (the flaps that close off the interior diameter of the adaptor) and which are "tethered" or attached and therefore also a "tether" (that portion of the flaps that directly interface with the interior walls of the valve device/enclosure) and which can respond to pressure differentials between the manifold and the enclosure and where the catheter can open the occluder responsive to manual insertion pressure upon the catheter and the tether retains the occluder.

In regards to claim 11, the device of Russo is fully capable of and does disclose in light of the understanding of one or ordinary skill in the art that the air flow rate in the device is responsive to negative pressure, i.e. flow is known to follow negative sloped pressure gradients, the greater/steeper the gradient the greater the flow rate induced by the negative pressure introduced. (See flow illustrated in fig 6 & supporting text.)

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russo as applied to claim 6 above, and further in view of Reynolds (US 5370610).

Russo substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a filter to filter airflow provided to the cleaning enclosure. However, Reynolds disclose such (# 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made,

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it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the device of Russo. The suggestion/motivation for doing so would have been to reduce the possibility of infecting the patient by filtering out bacteria (See Reynolds col. 9 line 50). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russo & Reynolds as applied to claim 8 above, and further in view of Loescher et al (US 5005568).

The suggested device substantially discloses the instant application's claimed invention, to include a valved opening (62 of Reynolds) but does not explicitly disclose the use of a valve in conjunction with the filter in the same opening. However, Loescher disclose such (See the filter/valve combination). The references are analogous since they are from the same field of endeavor, the medical/respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Loescher and used them with the suggested device. The suggestion/motivation for doing so would have been to have better control over the air being permitted to enter the medical device's

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interior. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russo as applied to claim 11 above, and further in view of Reynolds.

Russo substantially discloses the instant application's claimed invention, but does not explicitly disclose a filtered opening to ambient in the body of the cleaning enclosure. However, Reynolds disclose such (See # 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the device of Russo. The suggestion/motivation for doing so would have been to reduce possible bacterial contamination during use/operation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

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Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6227200. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a respiratory suction apparatus/system comprising a suction catheter with a protective sheath, a manifold with a distal adapter having a collar and a valve device for isolating the distal end of a catheter from a manifold.

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Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6165168, 5792113, 5769093, 5738091, 5735271, 5730123, 5715815, 5613663, 5385560, 5348542, 4691702, 4622964, 4529003, 3710942

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



June 20, 2002



DENNIS RUHL
PRIMARY EXAMINER